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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBI-6043CCPCPA	1842

7590

05/20/2002

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/399,083

Applicant(s)

Calderwood et al.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 18, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, and 46-52 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, and 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on January 18, 2002.

Claims 1-8, 10-11 and 46-52 are pending in this application.

The following rejections are withdrawn:

1. The rejections under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments.
2. The rejection under 35 U.S.C. 102(e) over U.S. Patent No. 6,001,839 is withdrawn in view of the amendment. Applicants amended the claims to delete the term "optionally" as applied to the substituents on ring A thereby requiring that ring A is always substituted. Further, applicants deleted the group -OH from the substituent list and therefore, the claim is not anticipated by the reference.
3. The provisional obviousness-type double patenting rejection over Application No. 09/381,036 is rendered moot because applicants submit that the application is abandoned.

The following rejections are under new grounds:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-8, 10-11 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The definition of L in claim 1 was amended (in paper no. 13, filed on September 28, 2000) to include $\text{-NHC(O)R}_{130}\text{-}$ and $\text{-NHSO}_2\text{R}_{130}\text{-}$ wherein R_{130} is an aliphatic group, however, this definition of L is not described in the specification within the genus. Applicant referred to Examples 185-187 (page 174) and 290-294 (pages 205-208) in the specification wherein the species contain a $\text{-NH-SO}_2\text{-CH}_2\text{-}$, $\text{-NH-C(O)-CH}_2\text{-}$ or $\text{-NH-SO}_2\text{-CH=CH-}$ groups in place of $\text{-L-(CH}_2\text{)}_j\text{-}$ of the genus, as support for the instant amendment. First, the $\text{-CH}_2\text{-}$ portion of the above groups may be representative of $\text{-(CH}_2\text{)}_j\text{-}$ which separates L and R_3 in the generic structural formula. Secondly, examples having $\text{-CH}_2\text{-}$ or -CH=CH- are not sufficient to form support for the broad term "aliphatic group" which can include carbon chain having any number of carbon atoms. Further, these definitions ($\text{-CH}_2\text{-}$ or -CH=CH-) are disclosed as being only part of the specific compounds and are not disclosed to be part of the genus.

Applicant further relied upon the originally filed claim 11 which contained the groups " -NHC(O)R- " and " $\text{-NHSO}_2\text{R-}$ " to support the instant recitation in claim 1. However, R is defined to be a monovalent substituent according to the disclosure and the original claims and not a 'divalent group' as considered by applicants (see the remarks on page 15 of paper no. 13, third paragraph). Therefore, there is no support in the specification for the addition of the R_{130} variable

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defined to be a “(divalent) aliphatic group”, to the generic claims or for the introduction of the L values of $\text{-NHSO}_2\text{CH}_2\text{-}$, $\text{-NHC(O)CH}_2\text{-}$ or $\text{-NHSO}_2\text{CH=CH-}$ to the entire genus. This moiety is not described within the genus of the structural formula and the myriad of permutations that are present within the genus do not include all of the permutations possible of adding the instant L, and thus, the genus may result in species that were not contemplated. Further, written description of species would not support claims to the generic element. “Disclosure of Two species in prior application did not provide written description to generic claims added in CIP”, see *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998).

Claim Rejections - 35 U.S.C. § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10-11 and 46-47 are rejected under 35 U.S.C. 103(a) as being obvious over Calderwood et al., U.S. Patent No. 6,001,839.

The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in col. 2 wherein R_3 is represented by formula (a) and the species in col. 7-10. The compounds are taught to be useful as pharmaceutical therapeutic agents having protein kinase inhibition activity, see the entire document. The claims differ from the reference by reciting a specific species and/or a more limited genus than the reference. Particularly, the instant claims differ from the reference by reciting that ring A is

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substituted by substituents such as halogen, aliphatic group, etc. The reference also teaches that the phenyl group of the R₃ is further substituted with alkyl, alkoxy, halo, etc. and provides examples wherein the substituent on the phenyl is methoxy or hydroxy. The substituent list in the instant claims does not include alkoxy or hydroxy, however, the reference clearly teaches that alkyl, alkoxy, halo, hydroxy, etc. are equivalent by disclosing them as alternative substituent groups on the phenyl ring. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter

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disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

A rejection under 35 U.S.C. 103(a) was applied to claim 46 in the previous office action over Calderwood et al., WO 98/41525 which belongs to the same patent family as US'839. Applicant arguments traversing the rejection of the previous office action are fully considered but they were not deemed to be persuasive. Applicant cites MPEP § 2144.08 and argues that the scope and contents of the prior art are too broad as compared to the species in the instant claims. This is not deemed to be persuasive because the instantly claimed species of claim 46 differ from the reference compounds only by the substituent on the phenyl ring. Specifically, the instant compounds have a fluoro substituent on the phenyl whereas the reference discloses species wherein the phenyl is substituted by methoxy or hydroxy. The reference, however, teaches the equivalence of methoxy, hydroxy, fluoro, etc. by disclosing them as alternatives on the phenyl ring. Further, the instant claims include alkyl substituents, e.g., methyl, on the phenyl ring A.

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The reference discloses many species wherein the phenyl ring is unsubstituted, see e.g., the species in col. 9, lines 24-25. The instant compounds differing from the reference compounds by having a methyl substituent are homologs of the reference compounds and it is well established in the art that compounds that are structurally homologous to the prior art compounds are *prima facie* obvious, in the absence of unexpected results.

It is to be noted that rejection under 35 U.S.C. 103 is proper where the subject matter claimed “is not *identically* disclosed or described” in the prior art, and the prior art directs those skilled in the art to the compounds, without any need for picking, choosing, and combining various disclosures. See *In re Shaumann et al.*, 572 F.2d 312, 315, 316, 197 USPQ 5, 8, (CCPA 1978). Further, the reference teaches integrin antagonistic activity for the compounds, which is sufficient to one of ordinary skill to make the claimed compounds because similar properties are normally presumed when compounds are very close in structure. *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976). “The question under 35 U.S.C. 103 is not merely what the reference expressly teaches but what it would have suggested to one of ordinary skill in the art at the time the invention was made.”

“Structural relationships provide the requisite motivation or suggestion to modify known compounds to obtain new compounds.” See *In re Duel*, 51 F.3d at 1558, 34 USPQ2d at 1214. The closer the physical and chemical similarities between the claimed species or subgenus and any exemplary species or subgenus disclosed in the prior art, the greater the expectation that the claimed subject matter will function in an equivalent manner to the genus. See *In re Dillon*, 919

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F.2d at 696, 16 USPQ2d at 1904. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties."

In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). Reference must be considered, under 35 U.S.C. 103, not only for what it expressly teaches but also for what it fairly suggests; all disclosures of prior art, including unpreferred embodiments, must be considered in determining obviousness. *In re Burckel*, 201 USPQ 67 (CCPA 1979).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-11 and 46-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,001,839. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because the instantly claims substantially overlap the reference claims. The same reasons provided under 35 U.S.C. 103(a) rejection apply here.

Claim Objections

Claims 1 and 6 are objected to because of the following informalities:

In claim 1, page 4, line 16, following the proviso statement, the term “and” is confusing because it creates ambiguity by coupling the definitions of R_4 and R_5 with the proviso. Deletion is suggested.

In claim 6, line 8 ends with a period, which is in the middle of the claim. Replacing with semicolon is suggested.

Appropriate correction is required.

Allowable Subject Matter

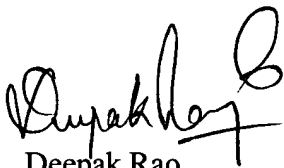
Claim 52 is allowed. The closest reference US'839 does not teach or fairly suggest the instantly claimed species, wherein the second phenyl ring is substituted with a 2-OCF₃. The reference does not teach that the phenyl ring of R_5 be substituted with a haloalkoxy group.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner

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can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

Deepak Rao
May 17, 2002